DP1 Ultrasonic Pocket Doppler User Manual
About the Manual
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Statement
This manual will help you understand the operation and maintenance of the product properly. Please note that the product must be used correctly and must comply with this manual. Users who do not comply with this manual may result in the unit not functioning properly or an accident in which PT. Sinko Prima Alloy Instrument. (hereinafter PT. Sinko Prima Alloy) cannot be held responsible. PT. Sinko Prima Alloy owns the copyright of this manual. Without prior written approval from PT. Sinko Prima Alloy. All materials related to this manual may not be photocopied, reproduced, or translated into other languages.
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The user should understand that nothing in this manual provides express or implicit permission to the user. All rights or licenses to the intellectual property of PT. Sinko Prima Alloy.
PT. Sinko Prima Alloy reserves the right to modify, update and explain this manual.

Responsibility of the Manufacturer
PT. Sinko Prima Alloy only considers itself responsible for any effect on the safety, constraints and equipment performance of the unit, if:
The assembly, extension, re-adjustment, modification or repair operations are carried out by a person authorized by PT. Sinko Prima Alloy and electrical installations in accordance with National Standards.
The instrument is used according to the instructions for use. PT. Sinko Prima Alloy will provide requests for circuit diagrams, part lists, descriptions, calibration instructions or other information on individual repairs to repair components of the unit appointed by PT. Sinko Prima Alloy as a component that can be repaired by service personnel.

Product Information
Product Name: Ultrasonic Pocket Doppler
Model: DP1

Terms in the Manual
This manual is intended to provide a basic concept of security measures.

Warning
A Warning label suggests a specific action or situation that results in personal injury or death.

Attention
A Caution label suggests an action or situation that results in product damage, inaccurate data or the cancellation of a procedure.

Notes
A Note proves useful information in terms of a function or procedure.

Security Measures

CAUTIONS

Federal (US) law restricts this device to sale by or on the orders of a physician.

Notes:
This manual is written to protect the maximum settings. Therefore, your model may or may not have the indicators and functions described, depending on what you ordered.

This unit uses internal power and has an IEC.EN 60601-1 Type BF safety. The type of protection BF means that the connection between the unit and the user meets the electrical and dielectric leakage safety standards of IEC.EN 60601-1. **WARNING** and **CAUTION** messages must be followed. To avoid possible injury, follow all instructions when operating the unit.

CAUTIONS

1. Only used by health practitioners on doctor's orders.
2. Before the DP1 is determined for personal use, the user must receive proper instructions or training.
3. Ultrasonic Pocket Fetal Doppler does not demonstrate preterm delivery or prevention of preterm birth.
4. The Doppler unit is a tool for healthcare practitioners and should not be used in the setting of normal fetal detection. It is not intended for treatment.
5. Placement of the ultrasound transducer on the abdomen is essential for obtaining the fetal heartbeat as opposed to the mother's heartbeat or sounds from the abdomen. Users must receive proper unit placement technique training either through acceptable Ob/Gyn training and individual circumstances or training from a physician and have been trained in unit placement.
6. The unit is not explosion proof and cannot be used near flammable objects.
7. Magnetic and electric fields can affect the unit's ability to properly. For this reason, ensure that all devices operating in the vicinity of the unit comply with EMC regulatory requirements. X-ray equipment and magnetic resonance imaging (MRI) devices can emit high levels of electromagnetic radiation.
8. We recommend that ultrasound exposure be kept as low as possible. This is really considered good practice and should be observed at all times.
9. Do not use the unit in conjunction with high-frequency surgical instruments and do not use the unit in the vicinity of magnetic resonance imaging (MRI) equipment which can emit high electromagnetic radiation.
10. The unit is not protected against defibrillation.
11. **ELECTRIC SHOCK HAZARD-** Do not attempt to change the battery when your hands are wet.
12. Do not connect any equipment or accessories that are not approved by the manufacturer or do not meet IEC 60601-1 standards to the unit. Use for unauthorized equipment or accessories has not been tested or supported and operation of the unit and safety are not guaranteed.
13. The use of accessories outside of the manufacturer's specifications may result in increased electromagnetic emissions or reduced electromagnetic resistance of the unit.
14. Units must not be used adjacent to or stacked on top of each other and if adjacent or stacked use is required, the units must be considered to ensure the operation to which they are to be used.
15. Electro-medical equipment requires installation and is put into service in accordance with the EMC information provided in this manual.
16. Radio communication equipment whether portable or cellular affects electrical equipment. See the **Recommended Distance section.**
17. Do not repair or maintain any device or accessory that is being used with a patient.

CAUTIONS

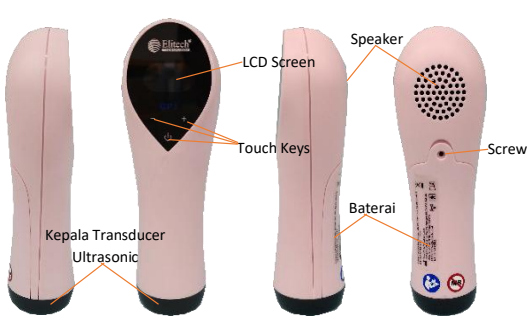
1. Provide service to professional technicians.
2. Store the device in a clean environment and avoid vibration during storage.
3. Do not sterilize Doppler with steam or gas.
4. **Electromagnetic Interference** - Ensure that the environment in which the device is operated is not adjacent to strong electromagnetic sources, such as radio transmitters, cellular telephones, etc.
5. Prior to a Doppler examination, check for any visible damage to the unit and probe that could endanger the patient/operator or machine performance. If damage is found, replace it with a decent one.
6. The following safety checks must be carried out every two years or as determined in the testing and inspection process by a qualified person who has adequate training, knowledge and practicality to carry out these tests.
   - Check equipment for mechanical and functional damage.
   - Check the security label.
   - Check equipment for mechanical and functional damage.
   - Check security labels that are relevant and easy to read.

   The leakage current should not exceed the limit. Data must be recorded in unit records. If the unit does not function properly or fails during testing, the unit must be repaired.
7. Devices and accessories must be disposed of in accordance with regulations after their lifetime, or may be returned to a dealer or recycling plant or appropriate disposal according to hazardous waste. Do not dispose of the unit together with household waste.

- **Introduction**

Purpose of Use / Indications for Use
The DP1 is a device intended for detecting the fetal heartbeat. The DP1 is intended to be operated by a professional and has been trained by a doctor for use by pregnant women in hospitals, clinics or at home.

Feature
- Detect and display FHR
- Fetal heartbeat sound Heartbeat
- Auto power off in ±2 minutes
- Sound level setting button
- Sound level setting
- Heart rate signal intensity icon
- Battery indicator
- Low battery warning



LCD Display & Touch Keys

Items	Description	
1	Heart rate	Heart rate indicator and flashes when it detects a heartbeat
2	Heart rate signal intensity indicator	This indicator is displayed on the left side of the screen and has three states: empty, half empty and full. Which respectively represent low, medium and high fetal heart signal intensity.
3	Heart rate indicator	Displays the fetal heart rate in the range from 50 bpm to 240 bpm. When the fetal heart rate is out of range,
	Volume indicator	The volume number is displayed in the center of the screen, the same area as the FHR Numeric. The volume display setting will appear for 0.5 seconds, then the display will return to the FHR numeric display. Sound volume ranges from 0~7.
4	Battery Indicator	The battery indicator is displayed on the right side of the screen. There are 5 battery levels, represented by 0~$ panels. If the battery is empty then the icon will flash.
5	Volume increase touchpad	Touch and hold the button briefly to increase the volume.
6	Volume reduction touchpad	Touch and hold the button briefly to decrease the volume.
7	Touchpad On/Off	When doppler is off, touch and hold this button to turn on. When doppler is on, touch and hold this button to turn it off.

Battery
The DP1 uses 2 AA lithium batteries. Battery specifications LR6, AA 1.5V

Notes:
You can use AA lithium batteries for the same specifications and can be purchased at the nearest store.

- **Basic Operation**

Notes:
To ensure the doppler is working properly, please read this section and the **Precautions section** before operating; follow the steps when connecting all components.

Opening and Checking Packages
Open the Package, carefully remove the Doppler and accessories. Take care of the packaging for transportation or storage at a later date. Check the components with the Packing List.
Check all External Damage.
Check all cables and accessories.
If there is a problem, contact you or the distributor directly.

Battery Installation.
a. Remove the screw with a plus screwdriver and remove the battery cover.
b. Insert the battery into the battery compartment carefully. Make sure the positive and negative poles are installed correctly, for installation can be seen in the battery compartment.
c. Install the battery cover and lock with screws.

Battery removal/installation
a. Remove the screw with a plus screwdriver and remove the battery cover
b. Take the battery that has been used, you can immediately replace it with a new one, make sure the battery is installed correctly
c. Install the battery cover and lock with screws

CAUTIONS

1. Turn off Doppler before removing battery
2. Replace alkaline batteries with batteries provided by the manufacturer or buy in stores according to the required specifications. See the product specifications section for detailed battery specifications.
3. If the battery is not installed properly, the Doppler will not work properly or it will be damaged
4. Do not disassemble the shorted battery
5. Do not recharge the battery
6. Do not throw the battery in fire or water
7. Do not stick metal objects on the battery circuit
8. Do not combine and use batteries with different types
9. Do not solder the battery directly. If you need soldering and welding, consult our technician for a suitable method
10. Don't overuse the battery
11. To replace the battery, follow the product instructions for use
12. Keep the battery away from children. If swallowed, contact a doctor immediately
13. Store the battery in a dry and cool place. Do not store the battery at a temperature of 45°C and above or at a humidity of 75% and above
14. Dispose of batteries according to regulations according to IEC61429 for standard disposal if necessary
15. Remove and store the battery in a cool, dry place if the Doppler is not used for a long time
16. A battery that has a lifetime. If the Doppler battery usage becomes shorter than normal, the battery life has expired. Replace the battery with a new battery with the same specifications as the manufacturer.

Turn on
Press the On/Off button for a few moments while the Doppler is off and the Doppler will display a lit display before switching to a test display

turn off
Press the On/Off button for a while while Doppler is on and Doppler will be off. If Doppler is not used for 2 minutes, Doppler will turn off automatically

- **FHR detection**

Before using Doppler to look for FHR, you should always make sure the Doppler is in good condition and if any damage will affect patient safety and the function of the device. If damage is found, discontinue use and replace with a new one.

Procedure for detecting FHR
a. Patient lying face up
b. Apply the gel on the surface of the ultrasonic Doppler transducer and turn on the Doppler
c. Touch the patient's abdomen to determine the location of the fetus
d. Apply Doppler on the patient's abdomen and rotate it around the fetus until a clear heart sound is obtained and the FHR number is stable

Notes:
1. Don't mistake the mother's heart rate with the fetal heart rate
2. Do not use gloves to touch the screen. If there is water and gel on the finger, please clean it first or touch will have an effect

The best way to find a heartbeat signal
1. The easiest and fastest way: refers to the position of the fetal heart at the last position detected by the doctor as a reference and Doppler movement around that position slowly until the best FH signal is found
2. The position of the fetal heart can change when the fetus moves in the uterus. You can confirm the position of the fetus in advance according to the uterine fundus (top of the uterus) at different weeks of pregnancy
   - At the end of the 12th week of gestation, the height of the uterine fundus is 2-3 fingers above the symphysis pubis (about 2-3 cm).
   - At the end of the 16th week of gestation, the height of the uterine fundus is midway through the symphysis and the center of the uterus
   - At the end of the 20th week of gestation, the height of the uterine fundus is 1 cm below the center
   - At the end of the 24th week of gestation, the height of the uterine fundus is 1 cm above the center of the uterus
   - At the end of the 28th week of gestation, the height of the uterine fundus is 3 cm above the center
   - At the end of the 32nd week of gestation, the height of the uterine fundus is between the xiphisternum and the center of the uterus
   - At 36 weeks of gestation, the height of the uterine fundus is 3 cm below the xiphisternum

The clarity and volume level of the fetal heartbeat is obtained from the fetal back. Fetal movement is usually the movement of the fetal limbs. So, if the movement of the fetus is often obtained from the right abdomen. The possibility of the fetal back is on the left and vice versa. You can find the fetal back based on the fetal movement
If the birth is head down (cephalic), the fetal heart is between the right or left of the center

Steps to Find Fetal Heartbeat
Position the patient in a supine and relaxed position >> Confirm the fetal position by hand >> Apply a little gel to the Doppler >> Place the Doppler on the patient's abdomen and start looking for the fetal heart >> The fetal heart can be found when the Doppler sounds "Boom-Boom-Boom "

CAUTIONS

1. The Doppler has an IP22 protection system that is water resistant. Do not drop the unit into the water
2. Doppler is very subtle and sensitive. It is expected to be careful when carrying to avoid falling on the ground or other hard surfaces. All forms of damage caused by falling are not covered by the warranty
3. Keep the gel away from children. If swallowed, contact a doctor

Notes:
1. The best heart rate quality is only obtained when the Doppler is placed where the signal is best detected
2. Do not place the Doppler near the placenta or the central bloodstream
3. If the fetus is in a head-down (cephalic) position and the mother is in a supine position, the sound of the heartbeat is most pronounced in the middle below the navel. During the examination, prolonged supine position should be avoided, to avoid high blood pressure. Providing a bolster or pillow under the patient's head or feet can help reduce this risk
4. If you do not get an optimal heart rate signal, it does not guarantee the accuracy of the reading. If the FHR (Fetal Heart Rate) reading does not match the sound of the heartbeat, the heartbeat sound from the reading will prevail
5. When worn on a patient, the Doppler temperature may feel slightly warm (<2°C(35.6°F)) above room temperature. When not in use, the Doppler temperature may be slightly (<5°C(41°F)) above room temperature.

After Use
1. Turn off Doppler
2. Clean the remaining gel from the patient and probe with a soft cloth or tissue

Care and Cleaning
Care
Before use, check the completeness and safety of the user or Doppler function. In case of damage, contact the manufacturer for immediate service or replacement
All Doppler checks, including function and safety checks, must be carried out by trained personnel, every check is carried out every 12 months and after every service. And the safety check should include leakage current test and insulation test. In addition to the above requirements, comply with local regulations regarding maintenance and measurement. The accuracy of the FHR reading is determined by Doppler and can be set by the user, if in doubt about the FHR reading, take the measurement by another method, such as a stethoscope or contact your local distributor or manufacturer for assistance.
Doppler is easily damaged and must be handled with care. Clean the rest of the gel from the Doppler after each use. Regular use of the unit, can help extend the life of the Doppler
Replace accessories such as batteries when they run out. If one of the accessories is damaged, read the Product information section for details and buy a new one

Cleaning
Before cleaning, turn off Doppler. Keep the surface of the body clean and free from dust and dirt. Clean the body with a soft dry cloth. If possible clean with a cloth dampened in soapy water, ethanol (75%) or isopropanol (70%). Then wipe with a dry cloth.

CAUTIONS

1. Do not use harsh solvents such as acetone
2. Never use objects that can steal wood or steel brushes
3. The Doppler is protected and has splash protection with an IP22 rating. Do not drop the Doppler directly into the water
4. Do not give any solution after cleaning the surface

Disinfection
On normal surfaces, Doppler does not need disinfection. If the surface is dirty, clean the unit and then disinfect the unit with a soft cloth and dampen it with ethanol (75%) or isopropanol (70%). Then wipe with a dry cloth

CAUTIONS

Do not dampen Doppler in a disinfectant

Sterilization
Do not sterilize Doppler

Notes:
After cleaning or disinfection, check the Doppler function. If any problems are detected, contact the manufacturer or service before using again

Item Check	Method
Visual Check	Check Doppler for any damage
Function check	Check Doppler, whether the bias is turned on normally or not (See how to turn it on and off). When Doppler is turned on, check whether the display panel is lit normally like **LCD Display and Touch Key:** touch the ultrasound transducer head and check whether it can produce clear sound or not

Product Specification
Product Information

Product name	Ultrasonic Pocket Doppler
Model	DP1

Complied Standards

IEC 60601-1:2005, EN 60601-1:2006/A1:2003, IEC 60601-1-2:2004<IEC 60601-2-37:2015, EIC 61266:1994

Classification

Anti Shock Type	AA Battery Power
Anti Shock Class	Type BF
Water Resistance Class	IP22, resistance to drops or splashes when the BATTERY COVER is tilted 15°
Resistance To Flammable Gases Class	The unit cannot be used near flammable gas
Work system	Continously
EMC (Electromagnetic Compatibility)	CISPR 11 group 1 Class B

Physical Specification

Size	Length x Width x Height: 48 mm(P) x 39 mm(L) x 147 mm(T)		
Weight	90 g (excluded battery)		
LCD	size	1.1" inch	
	Display	• FHR • Battery Level • Signal Intensity	• Sound volume level • FH Icon
Gel	pH: 5.5~8.0 Acoustic Impedance: 1.5 x 10 ^{6} Pa.s/m ~1.7 x 10 ^{6} Pa.s/m (35°C/95°F)		

Environmental conditions

Working:	Temperature: +5°C-40°C Humidity: 15%-80% Atmosphere Pressure : 700hPa
Transport and storage	Temperature: -20°C-55°C Humidity: ≤95% Atmosphere Pressure : 700hPa

Note: the time it takes Doppler to use from the minimum temperature is 2 hours. The time required for Doppler to cool from the maximum storage temperature until it is ready for use is 2 hours

Product Specification

FHR (fetal heart rate)	Range : 50bpm~240bpm Accuracy: ±3 bpm Note: FHR measurement results may not be accurate if Doppler measurement is out of range
FHR Resolution	1 bpm
Audio Output	Output: 2W, Noise: ≤45 dBa
Overall sensitivity	>110 dB
Auto Off	The unit will turn off automatically if the Doppler does not receive a signal or is not operated for 2 minutes
Bluetooth	Transmission distance (without obstruction) >5m (inside the room depending on the building structure and material
Ultrasound	Normal Frequency: 3 Mhz Working Frequency: 3 Mhz P_<1 MPa, Lob <10 mW/cm ^{2} Ispta < 100 mW/cm ^{2}, Isata < 10mW/cm ^{2} Isppa.3 < 190 mW/cm ^{2}, Ispta.3 <94mW/cm ^{2}

	Effective Radiation Area: 490 mm2 ±15% Working Mode: Pulse wave

Battery Specifications

Specification	2x AA 1.5V Alkaline Batteries (AA, LR6, 1.5V)
Wear Resistance	≥6 hours

Summary table

(For systems whose global maximum value does not exceed 1.0)

System : DP1 Ultrasonic Pocket Doppler

Model (Mhz)	$I_{spta.3}$ (mW/cm ^{2})	IT Type	IT Value	MI	$I_{spta.3}$ (W/cm^2)
DP1 CD3.0	5.69	TIS	0.05	0.01	0.02
		TIB	0.01		

Order Information

CAUTIONS

Only supply parts from the manufacturer can be used in Doppler

Part	Part Number
Main Unit	
DP1 Doppler (Non Bluetooth)	02.06.262535
Accessories	
AA Alkaline Batteries	01.21.064086
Bag	01.56.465616
Ultrasound Gel	01.57.14019

Ultrasound Intensity and Safety

Ultrasound in Health

The use of diagnostic ultrasound has proven to be a very useful tool in the world of medical practitioners. Given its usefulness for reading or non-invasive examination and medical diagnosis, including fetal observation. Questions about clinical safety arise with regard to the intensity of use of ultrasound. There are no easy answers to safety questions surrounding the safe use of ultrasonic equipment. The application of ALARA (As Low As Reasonably Achievable) serves as a rule of thumb which helps you to get reasonable results with the lowest possible ultrasonic output. The American Institute of Ultrasonic In Medicine (AIUM) states that over a 25 year period of use, no biologic effects were found on the patient or instrument operator, the benefits of using diagnostic ultrasound clearly outweigh the risks.

Ultrasound Safety and the ALARA Principle

Ultrasonic waves can produce heat energy, because it can cause tissue heating. Although this effect is very low on Doppler, it is important to know how to control and limit patient exposure. The government states that there are no adverse effects on the use of ultrasound diagnostics, however, the level of subtle exposure is always limited, As Low As Reasonably Achievable (ALARA).

Explanation from MI/TI

MI (Mechabical Index)

Cavitation is generated when the ultrasonic wave passes through and contacts the tissue, resulting in local heating. The phenomenon is determined by the acoustic pressure, the spectrum, the focus of the transmission mode and factors such as the state and nature of the network. This mechanical effect is a threshold phenomenon that occurs when a certain ultrasonic output level is exceeded. Although there are no known side effects on exposure to the intensity of ultrasound waves. Diagnostic ultrasonic instruments that have been reported the threshold for caviatsy has not yet been determined. Generally, the higher the acoustic pressure, the greater the potential mechanical bioeffect

AUIM and NEMA developed a Mechanical Index (MI) to show potential mechanical effects. MI is defined as the ratio of the peak acoustic pressure (to be calculated by the network acoustic attenuation coefficient of 0.3 dB/cm/Mhz) to the acoustic frequency.

MI = Pr,α

Fawf x CMI

CMI = 1(MPa/Mhz)

IT (Thermal Index)

Tissue heating is caused by absorption of ultrasound when ultrasound is used. The temperature rise is determined by acoustic intensity, open area and objects that can absorb tissue heat.

To demonstrate the potential for temperature increases caused by thermal effects, AUIM and NEMA formulated a thermal index (TI). It is defined as the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1°C (1.8°F)

According to the different physical properties of the thermos network, IT is divided into three kinds: TIS, TIB and TIC. TIS is Soft Tissue Thermal Index): this provides an estimate of the potential for temperature rise in soft tissue or similar. TIM (Bone Thermal Index): This gives an estimate of the potential temperature rise when the ultrasonic beam passes through soft tissue and the focus area is around the bone. TIC (Cranial Bone Thermal Index): this provides an estimate of the potential temperature rise in the skull or superficial bones

Measurement Uncertainty

Uncertainty in measurement is predominantly systematic in origin; negligible random uncertainty is compared. The overall systematic uncertainty is determined as follows:

1. Hydrophone Sensitivity: ±12 percent for intensity, ±6 percent for pressure. Based on hydrophone calibration report by ONDA. The uncertainty is specified in ±1 dB in the 1-15 Mhz . frequency range
2. Digitizer: ±0.3 percent for intensity. ±0.15 percent for pressure. Based on the stated accuracy of the 8-bit resolution of the Agilent DSO6012 Digital Oscilloscope and the signal-to-nise ratio of the measurements.
3. Temperature: ±2.4 percent for intensity uncertainty, ±1.2 percent for pressure uncertainty. Based on water bath temperature variation ± 1°C(1.8°F)
4. Spatial mean: ±3.5 percent for intensity, ±1.75 percent for pressure
5. Non-Linear Distortion: N/A

No nonlinear propagation effect was observed. Since all the above error sources are independent, they can be added on an RMS basis, giving a total uncertainty of ±12.73 percent for all reported intensity values, ±6.37 percent for all pressure values ±12.6 percent for the Mechanical index, ±12 percent uncertainty, 73 percent for power, ±0.15 percent for center frequency, ±6.87 percent for MI

Instructions for Wise Use

Although no adverse effects in patients caused by exposure to ultrasonic diagnostic equipment have ever been reported, there is potential that these side effects may be identified in the future. Therefore, ultrasound should be used with caution. High acoustic output levels and long exposure times should be avoided when obtaining the necessary clinical information.

Reference for Acoustic Output and Safety

1. "Bioeffects and Safety of Diagnostic Ultrasound" issued by AIUM in 1993
2. "Medical Ultrasound Safety" issued by AIUM in 1994
3. "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3" issued by AIUM/NEMA in 2004
4. "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment, Revision 2" issued by AIUM/NEMA in 2004
5. "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in 2008.
6. "Medical electrical equipment—Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment"issued by IEC in 2007

Acoustic Output Reporting Table for Track 1 EIC60601-2-37(EIC60601-2-37, Edition 2.1, 2015-0, table 201.103)

Transducer Model: DP1, Operational Mode: PW mode

Index label		*MI*	*TIS* Above Surface	*TIS* Below Surface	*TIB* Above Surface	*TIB* Below Surface	*TIC*
Maximum Index Value		0.01	0.05		0.01		N/A
Index Component Value			N/A	0.05	NA	0.01	
Parameters A	*pr.αat zMI (MPa)*	0.02					
	P (mW)		7.35		7.35		N/A
	P1x1 (mW)		N/A		N/A		
	zs(cm)			3.50			
	zb(cm)					3.70	
	zMI(cm)	3.7					
	zPII.α (cm) .α	3.70					
	fawf (MHz)	3.00	3.00		3.00		N/A
Other Informati	*prr (Hz)*	5000					
	srr(Hz)	N/A					
	npps	1					
	lpa.α at zPII.α (W/cm2)	0.02					
	lspta.α at zPII.α or zSII.α(mW/cm2)	5.69					
on							
	lspta at zPII or zSII (mW/cm2)	12.26					
	pr. at zPII (MPa)	0.0 4					

Acoustic Output Reporting Table for Track 1 (No Auto Scan Mode)

Transducer Model: DP1, Operational Model: PW

Acoustic Output			MI	ISPTA.3 (mW/cm^2)	ISPPA.3 (W/cm^2)
Global Maximum Value			0.01	5.69	0.02
Related Acoustic Parameters	Pr.3 (MPa)		0.02		
	W0 (mW)			7.35	8.97
	fc (MHz)		3.00	3.00	3.00
	Zsp(cm)		3.70	3.70	3.70
	Beam Dimension	X-6(cm)		2.50	2.50
		Y-6 (cm)		2.50	2.50
	PD (usec)		72.2 5		72.25
	PRF(Hz)		5000		5000
	EBD	Az. (cm)		2.50	
		ele. (cm)		2.50	
Operational Condition Control	Unchanged/Static				

Standard parameter of Contract List

IEC60601-2-37 Standard Parameters

Parameter	Note		parameter	Note
$p_{r.\alpha}$	Acoustic pressure step faction peak weakening		f_{awf}	Center Frequency, Working Acoustic Frequency
p_r	Peak Acoustic pressure step faction		X	-12dB Output Beam Dimension
P	Energy Results		Y	
z_s	Fine Tissue Heat Index Depth		t_d	Pulse duration
$P(z_s)$	Weakening of power yield		prr	Average Frequency of Pulse Repetition
$I_{ta.\alpha}(Z_s)$	Temporary Weakening of Average Intensity		d_{eq}	Radiant diameter comparison
z_{bp}	Saturation point depth		$I_{pi.\alpha}$ at max MI	Average Attenuation of Pulse Intensity from Maximum Point Mechanical Index
z_b	Bone Heat Index Depth		aprt _	-12dB Output Beam Area
$I_{pi.\alpha}$	Weakening of pulse intensity		MI	Mechanical Index
I_{pi}	Whole pulse intensity		TIS	Fine tissue heat index
$d_{eq}(Z_b)$	Comparison of Radiant Diameter from point Z_{sp}		TIB	Bone Heat Index
			TIC	Skull bone heat index

EMC Information

Electromagnetic Emission

Manufacturer's Instructions and Claims on Electromagnetic Resistance

DP1 Ultrasonic Pocket Doppler produces a specific electromagnetic environment, the use must ensure that the unit is used in such environments:

Emission Test	Adjustment	Instructions or help on the electromagnetic environment
RF emissions CISPR 11	Group 1	The DP1 Ultrasonic Pocket Doppler uses only RFC power for its functions. Therefore its RF emission is very low and does not pose any risk to nearby electronic equipment
RF Emissions CISPR 11	Class B	DP1 Ultrasonic Pocket Doppler is suitable for use in all companies including domestic companies and is connected directly to low voltage power
IEC/EN61000-3-2 . Harmonic Emissions	Not applicable	
Variable Voltage/Emission Increase or Fluctuation IEC/EN61000-3-3	Not applicable	

Electromagnetic Immunity

Manufacturer's Instructions and Claims on Electromagnetic Immunity

The DP1 Ultrasonic Pocket Doppler produces a specific electromagnetic environment. The user must ensure that the unit is used in environments such as:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8kV contact 15kV water	8kV contact 15kV water	The floor must be made of wood, concrete or ceramic if the floor is covered with synthetic material, the humidity must be at least 30%
Temporary Electrical Speed/ Burst IEC/EN61000- 4-4	±2kV for power supply lines ±1kV forinput/output lines	Not applicable	Not applicable
Surgical Operation IEC/EN61000- 4-5	± 1 kV line(s) toline(s) ± 2 kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short circuit faults and voltage changes in the power supply IEC/EN61000- 4-11	<5%UT(>95% dip inUT) for 0.5cycle 40%UT(60%dip in UT) for5 cycles 70%UT(30%dip in UT) for25 cycles <5%UT(>95% dip inUT) for 5s	Not applicable	Not applicable
Frequency Strength (50Hz/60Hz) Magnetic Field IEC61000-4-8	30 A/m	30 A/m	The frequency of the magnetic field strength must be at the level characteristic of the type of hospital environment

Electromagnetic Immunity

Manufacturer's Instructions and Claims on Electromagnetic Immunity

The DP1 Ultrasonic Pocket Doppler produces a specific electromagnetic environment. The user must ensure that the unit is used in environments such as:

Immunity Test	IEC 60601 test level	Adjustment Level	Instructions on the electromagnetic environment
Conducti onRF IEC61000-4-6	3 V rms 150 kHz ~80 MHz 6Vrmsc) in ISM bands between 0.15 MHz	3 V rms 150 kHz to 80MHz 6Vrmsc)in ISM bands between 0.15 MHz and80 MHz	Portable and Mobile RF communications should not be used near the SD1. Ultrasonic Pocket Doppler, cable included. The recommended distance is calculated from the difference in the transmitter frequency

	and80 MHz		
			Minimum Separation Distance *d* 1.2 *P* 150 _ kHz to 80 MHz *d* 1.2 *P* 80 _ kHz to 800 MHz *d* 2.3 *P800* _ kHz to 2.7 MHz *d*= 6/E Communicated Wireless RF devices (portable RF communication devices) including peripherals such as antennas, cables and external interfaces should not be used from a distance of 30cm (12 inch) to all parts of the DP1 Ultrasonic Pocket Doppler

Note1: at 80Mhz and 800Mhz, the higher frequency range is obtained.

Note2: Helplines may not work in all conditions. Electromagnetic propagation may not work in all conditions. Electromagnetic propagation affects the absorption and reflection of strictures, objects and people

[a] The field strength of fixed transmitters, such as radio station (cellular/cordless) telephones and radio equipment, amateur radio, AM or FM and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, the review of electromagnetic waves should be considered. If the field strength is measured at a location where the DP1 ultrasonic Pocket Doppler is supposed to be observed, additional steps may be required such as reorienting or moving the DP1 Ultrasonic Pocket Doppler.

[b] In the frequency range 150khz to 89 Khz, the field strength must exceed 3 V/m.

[c] ISM (industrial, scientific and medical) have a network between 0.15 MHz and 80 MHz 6,765 MHz to6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40.66 MHz to 40,70 MHz. Amateur radio signal beam 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz,21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Test table Specifications for Sheath Port immunity of RF wireless communication equipment

Test Frequency (MHz)	Network a) (MHz)	Service a)	Module b)	Maximum Power r(W)	Distance (m)	Immune level test (V/m)
385	380-390	TETRA 400	pulse module	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [C] ±5 kHz deviation on 1kHz sine	2	0.3	28
710 745 780	704-787	LTE Brand 13, 17	pulse modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE 5 band	pulse modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1, 3, 4, 25;UMTS	pulse modulation [b] 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth h, WLAN, 802.11 b/g/n, RFID 2450, LTE Brand 7	pulse modulation [b] 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	pulse modulation [b] 217 Hz	0.2	0.3	9

Note: If it is possible to achieve the Immunity Test Level, the distance from the transmitting antenna to the unit may be reduced to 1M. 1M test distance is obtained from EIC 61000-4-3

a. For other services, if the inner frequency uplink is included
b. Provider should pay for modulation using 50% heavy signal
c. As an alternative FM module, a 50% pulse module at 18Hz might be used because while it doesn't represent actual modulation it would be a bad case

Troubleshooting

Problem	Possibility	Solution
Failed to turn on and off	Low battery	Change the battery
	Failed to turn on Doppler	Correct the battery position
	Doppler not working	Touch on/off momentarily to turn on
Loudspeaker not working	The lowest sound level	Adjust volume
	Doppler not working	Contact the manufacturer
FHR does not show consistent results	There are powerful displays and sources such as high machine frequencies and mobile phones nearby	Doppler usage distance
	The position of the fetal heart rate changes due to movement	Change the best position to find the position of the fetal heart rate
	Friction between the Doppler and the patient's abdomen results in an error display	Find the best position to get the sound of the fetal heartbeat
Low sensitivity and too much noise	There are strong disturbances such as high frequency machines and mobile phones nearby	Keep the distance using Doppler
	Doppler is not used with ultrasound gel	Give some ultrasound gel
	Doppler is not placed in the best position	Change the reading position to find the position of the fetal heart rate
	Doppler not working	Contact the manufacturer

Warranty and service

Warranty

PT. Sinko Prima Alloy guarantees that PT. Sinko Prima Alloy has complied with the table specifications of the product and will be free from defects in materials and workmanship that occur within the warranty period

Warranty does not apply if:

a. Damage occurs due to handling when shipping expeditions
b. Damage caused by improper use or maintenance
c. Damage caused by changes or repairs by anyone not authorized by PT. Sinko Prima Alloy
d. Damage caused by accident
e. Replacement or removal of serial number labels and manufacture labels

If a product covered by this warranty is found to be defective due to faulty materials, components or defective workmanship and a warranty claim is made within the warranty period, PT. Sinko Prima Alloy at its sole discretion repairs or replaces damaged parts free of charge. PT. Sinko Prima Alloy will not provide replacement products for use when the defective product is being repaired

Contact Information

If you have any questions regarding maintenance, technical specifications or device malfunction, please contact your local distributor

PT. SINKO PRIMA ALLOY

Address : Pond osowilangun scenic block E8. Jl. Osowilangun No. 61, Surabaya

Email: admin@elitech.co.id

Website: http://elitech.co.id

No. Phone: 031 7432882

Symbol Definition

1	CE 0123	CE marking	10	EC REP	Authorized Representative e in the European Community
2		Disposal Method	11		Recyclable
3		Operating System Procedure	12		Read Manual Book
4		Warning	13	MR	The unit is sensitive to magnetic fields. Keep it!
5		BF Type Guard	14		Non-ionizing electromagnetic radiation
6	P/N	Part Number	15	IP22	Dustproof and waterproof degree is IP22(rainproof)

7	SN	Serial Number	16	Rx Only	US law restricts this product from being sold by a doctor's recommendation
8		Manufacture Date	17	FCC ID: SMQSD1ME AND	Federal Communications Commission: FCC ID: SMQSD1ME AND
9		Manufacturer			